Inert ingredient	Limits	Uses
* * *	* * *	* * *
Polymethylene polyphenylisocyanate, polymer with ethylene diamine, diethylene triamine and sebacoyl chloride, cross-linked; minimum number average molecular weight 100,000.	.....	Encapsulating agent
* * *	* * *	* * *

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[FR Doc. 95–18365 Filed 7–25–95; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Parts 185 and 186

[FAP 9H5587/R2144; FRL–4960–8]

RIN 2070–AB78

Tralomethrin; Food and Feed Additive Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes time-limited food and feed additive regulations for residues of the synthetic pyrethroid tralomethrin in or on the processed commodity tomato puree and animal feed tomato pomace, wet and dry. AgrEvo USA Co. (formerly Hoechst Roussel Agri-Vet Co.) requested these regulations pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) that would establish the maximum permissible levels for residues of the pesticide in or on the processed food commodity and animal feed.

EFFECTIVE DATE: This regulation becomes effective July 26, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 9H5587/R2144], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St. SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [FAP 9H5587/R2144]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: George T. LaRocca, Product Manager (PM) 13, Registration Division (7505C), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Rm. 259, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6100; e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 10, 1995 (60 FR 24815), EPA issued a proposed rule that gave notice that Hoechst-Roussel Agri-Vet Co. had submitted to EPA pursuant to section 409 of the FFDCA, 21 U.S.C. 348, food/feed additive petition (FAP) 9H5587 proposing to amend 40 CFR 185.5450 and 40 CFR part 186 by establishing time-limited food/feed additive regulations to permit residues of the insecticide tralomethrin, (S)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*S*)-2,2-dimethyl-3-[(RS)-1,2,2,-tetrabromoethyl]-cyclopropanecarboxylate, and its metabolites in or on the processed commodity tomato puree at 1.00 part per million (ppm) and the animal feed tomato pomace, wet and dry, at 1.50 ppm and 4.00 ppm, respectively.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted with the proposal and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the time-limited food and feed additive regulations will protect the public health. Therefore, the time-limited food and feed additive regulations are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register,** file written objections and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [FAP 9H5587/R2144] (including any objections and hearing requests submitted electronically as described

below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the document control number [FAP 9H5587/R2144], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in **ADDRESSES** at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Parts 185 and 186

Environmental protection, Administrative practice and procedure, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 6, 1995.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR parts 185 and 186 are amended as as follows:

PART 185—[AMENDED]

1. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

b. By revising § 185.5450, to read as follows:

§ 185.5450 Tralomethrin.

(a) A time-limited food additive regulation is established for the combined residues of the insecticide tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*S*)-2,2-dimethyl-3-[(*RS*)-1,2,2,2-tetrabromoethyl]-cyclopropanecarboxylate; CAS Reg. No. 66841-25-6) and its metabolites (*S*)-*alpha*-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-*alpha*-cyano-3-phenoxybenzyl(1*S*,3*R*)-3-(2,2-dibromovinly)-2,2-dimethylcyclopropanecarboxylate calculated as the parent in or on the following food commodities when present as a result of application of the insecticide to the growing crops:

Commodity	Parts per million	Expiration date
Cottonseed oil .	0.20	Nov. 15, 1997.

(b) A time-limited food additive regulation is established permitting residues of the pesticide tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*S*)-2,2-dimethyl-3-[(*RS*)-1,2,2,2-tetrabromoethyl]-cyclopropanecarboxylate; CAS Reg. No. 66841-25-6) and its metabolites (*S*)-*alpha*-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-*alpha*-cyano-3-phenoxybenzyl(1*S*,3*R*)-3-(2,2-dibromovinly)-2,2-dimethylcyclopropanecarboxylate calculated as the parent in or on the following food commodity resulting from application of the insecticide to tomatoes in accordance with an experimental program (34147-EUP-2). The conditions set forth in this section shall be met.

Commodity	Parts per million	Expiration date
Tomato puree .	1.00	June 1, 1997

(1) Residues in the food not in excess of the established tolerance resulting from the use described in paragraph (b) of this section remaining after expiration of the experimental program will not be considered to be actionable if the insecticide is applied during the term of and in accordance with the provisions of the experimental use program and feed additive regulation.

(2) The company concerned shall immediately notify the Environmental Protection Agency of any findings from the experimental use that have a bearing on safety. The firm shall also keep records of production, distribution, and performance, and on request make the records available to any authorized officer or employee of the Environmental Protection Agency or the Food and Drug Administration.

PART 186—[AMENDED]

2. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 348.

b. By adding new § 186.5450, to read as follows:

§ 186.5450 Tralomethrin.

(a) A time-limited feed additive regulation is established permitting residues of tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*S*)-2,2-dimethyl-3-[(*RS*)-1,2,2,2-tetrabromoethyl]-cyclopropanecarboxylate; CAS Reg. No. 66841-25-6) and its metabolites (*S*)-*alpha*-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-*alpha*-cyano-3-phenoxybenzyl(1*S*,3*R*)-3-(2,2-dibromovinly)-2,2-dimethylcyclopropanecarboxylate calculated as the parent in or on the following feed resulting from application of the insecticide to tomatoes in accordance with an experimental program (34147-EUP-2). The conditions set forth in this section shall be met.

Feed	Parts per million	Expiration date
Tomato pomace, wet.	1.50	June 1, 1997
Tomato pomace, dry.	4.00	June 1, 1997

(b) Residues in the feed not in excess of the established tolerance resulting from the use described in paragraph (a) of this section remaining after expiration of the experimental program will not be considered to be actionable if the insecticide is applied during the term of and in accordance with the provisions of the experimental use program and feed additive regulation.

(c) The company concerned shall immediately notify the Environmental Protection Agency of any findings from the experimental use that have a bearing on safety. The firm shall also keep records of production, distribution, and performance, and on request make the records available to any authorized officer or employee of the Environmental Protection Agency or the Food and Drug Administration.

[FR Doc. 95–18002 Filed 7–25–95; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 424

[BPD–709–FC]

RIN 0938–AF01

Medicare Program; Allowing Certifications and Recertification by Nurse Practitioners and Clinical Nurse Specialists for Certain Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period authorizes nurse practitioners and clinical nurse specialists, working in collaboration with a physician, to certify and recertify that extended care services are needed or continue to be needed. In addition, it sets forth the qualification requirements that a nurse practitioner or clinical nurse specialist must meet in order to sign certification or recertification statements. This final rule is necessary to implement section 6028 of the Omnibus Budget Reconciliation Act of 1989.

DATES: Effective Date: These regulations are effective on August 25, 1995.

Comment Date: Comments regarding the qualification requirements will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on September 25, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–709–FC, P.O. Box 7517, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, MD 21207.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–709–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Jim Kenton, (410) 966–4607.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1814(a) of the Social Security Act (the Act) requires specific certifications in order for Medicare payments to be made for certain services. Before the enactment of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239), section 1814(a)(2) of the Act required that, in the case of post-hospital extended care services, a physician certify that the services are or were required to be given because the individual needs or needed, on a daily basis, skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in a skilled nursing facility (SNF) on an inpatient basis.

The physician certification requirements were included in the law to ensure that patients require a level of care that is covered by the Medicare program and because the physician is a key figure in determining utilization of health services.

OBRA '89 was enacted on December 19, 1989. Section 6028 of OBRA '89 amended section 1814(a)(2) of the Act to allow, in the case of extended care services, a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility, but is working in collaboration with a physician, to certify and recertify that extended care services are needed or continue to be needed. This provision took effect upon enactment.

Current regulations located at 42 CFR part 424, concerning conditions for Medicare payments, specify that a physician must certify and recertify the need for services. Regulations located at § 424.20 provide Medicare Part A coverage for post-hospital SNF care furnished by a SNF or a swing-bed hospital only if a physician certifies and recertifies the need for those services. Section 424.20(a)(2) contains certification requirements for certain swing-bed hospital patients under which a physician must certify that transfer to a SNF is not medically appropriate. Also, § 424.20(e) provides that certification and recertification statements may be signed by the physician responsible for the case or, with his or her authorization, by a